ASA
American Soybean Association

September 21, 1999

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

In re Docket No. 98P-0683

Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease

Dear Sir or Madam:

The American Soybean Association ("ASA") generally supports the re-proposal of the proposed rule to authorize a health claim relating the consumption of soy protein to reduced risk of coronary heart disease although ASA believes that clarification of the scope of records review by investigators would be appropriate. The reproposed provision concerns the analytical methodology that would be applicable to identifying whether a product, carrying the soy protein health claim, contains the requisite amount of soy protein to qualify for the proposed claim.

ASA represents principally soybean farmers but the effort underlying this submission has been a collaborative project including the efforts and contributions of soybean processors and producers of soybean products that contain soy protein.

We agree with the proposal to measure soy protein content for compliance by measurement of iota! protein content using the appropriate methods of analysis published by AOAC for those products whose protein content derives exclusively from soy. For these products, FDA should specifically clarify in the preamble to the final rule as well as in its inspectional and field guidance that the collection of additional information from manufacturers' records is neither necessary nor permitted.

For those products that contain sources of protein other than soy and bear a health claim for soy, the ASA recognizes and supports the need for manufacturers to provide sufficient records to substantiate the claim and make such records available to appropriate regulatory officials on request. ASA also requests, however, that the agency clarify either in the language of the final rule or in the preamble to the final rule the scope of such document or records requests, as set forth in the current language of the proposed rule. To that end, the proposal provides a list of potential documents or records on which FDA could base calculations and then states "or other

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reasonable bases." ASA reads that language to be consistent with, for instance, FDA's original proposal that any entity making a health claim maintain records for inspection that would provide a "reasonable basis to substantiate the claim." ***See generally*** 61 FR 3885 (Feb 2, 1996). ASA requests that FDA clarify, when making the proposed rule final, that manufacturers must provide appropriate regulatory officials with information that provides a reasonable basis for concluding that the food may bear the claim. This will ensure that each manufacturer has the flexibility to satisfy that requirement for substantiation in an appropriate manner. For some entities, this could be limited to the levels of ingredients that contribute to the final product. In' sum, ASA wants to protect company records from unwarranted and unjustified inspection and duplication.

We are also requesting a response from the agency as to the circumstances that would precipitate a request for such records and that such records may be provided on site without the need for reproduction or duplication by the investigator.

Finally, we agree with the agency that assays that are more specific and accurate for soy protein may be developed that would permit amendment of the proposed rule and deletion of the record inspection requirement. We believe that, should such an assay be developed, the agency should commit to prompt amendment of the rule to provide for use of such assay.

Thank you for your consideration of our views.

Sincerely,

Marc Curtis

Marc Curtis
President